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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,131	11/10/2000	Ronald B. Gartenhaus	9598-30U1	4043

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/709,131	GARTENHAUS, RONALD B.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 14-17, 32-37 and 40-47 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 32-37 and 40-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. The Election filed May 17, 2004 in response to the Office Action of February 11, 2002 and the Response to the Communication mailed on August 25, 2005, filed December 27, 2005 are acknowledged and have been entered. Claims 32-37, 40-47 have been added and 1-13, 18-31, 38-39 have been canceled. Claims 14-17 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 32-37, 40-47 are currently under prosecution.

2. Applicant's election of the newly added Group drawn to antibodies is acknowledged. Applicant specifically states that claims to groups I, II, and IV-XIII have been canceled and that Applicant has not previously elected one of Groups I-XIII. Applicant requests that Examiner consider claims 32-47 as the elected group for prosecution on the merits and that Examiner consider claims 14-17 to be withdrawn from consideration. Given Applicant's clear election, claims 14-17 have been withdrawn from consideration as set forth above.

3. Upon review and reconsideration it is found that Restriction to one of the following inventions of the newly added claims is required under 35 U.S.C. 121:

Group 1. Claims 32-37, 40-41 are drawn to an antibody that binds to a portion of MCT-1, classified in Class 530, subclass 350+.

Group 2. Claims 42-45 are drawn to a method of making an antibody, classified in Class 514, subclass 2+. It is noted although claim 45 is dependent upon canceled claim 38, the subject matter of claim 45 appears to be related to the subject matter of claim 44 and therefore in the interests of compact prosecution, Examiner is assuming for examination purposes that the dependency of claim 45 on claim 38 is an inadvertent typographical error and that claim 45 meant to be properly dependent upon claim 44.

Group 3. Claims 46-47 are drawn to a method of determining whether a cell is a tumor cell *in vitro* as contemplated in the specification, classified in Class 435, subclass 7.1.

Group 4. Claims 46-47 are drawn to a method of determining whether a cell is a tumor cell *in vivo* as contemplated in the specification, classified in Class 424, subclass 130.1.

4. The inventions are distinct, each from the other because of the following
- Inventions 2-4 are materially distinct methods which differ at least in objectives, method steps and reagents. For example, Group 2 is drawn to a method of making an antibody which is a method requiring the use of a polypeptide to stimulate the immune response of an animal which is a method with very different objectives than methods of determining whether a cell is a cancer cell wherein different method steps, reagents, dosages, schedules used, response variables and criteria of success are required. Further, the method of Group 3 is drawn to an *in vitro* assay with very different objectives than the method of Group 4 drawn to an *in vivo* procedure wherein both of these methods require different reagents, different method steps, reagents, dosages, schedules used, response variables and criteria of success, one from the other.

The inventions of Groups 1 and 2-4 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP*, 806.05(h)]. In the instant case the antibody product as claimed can be used in a materially different process such as production of anti-idiotypic antibodies.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. It is noted that on March 13, 2006 Examiner called Gary Colby and requested that Mr. Colby elect an invention for examination per the restriction requirement above (see telephone interview of March 13, 2006). Mr. Colby said that he is unable to do a telephone election at this time and requested that the restriction requirement be mailed.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

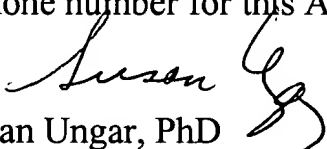
8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104.

Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.


Susan Ungar, PhD
Primary Patent Examiner
March 13, 2006